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AN EMPIRICAL METHOD FOR MATERIALITY: WOULD CONFLICT OF INTEREST DISCLOSURES CHANGE PATIENT DECISIONS?

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The law has long been concerned with the agency problems that arise when advisors, such as attorneys or physicians, put themselves in financial relationships that create conflicts of interest. If the financial relationship is "material" to the transactions proposed by the advisor, then non-disclosure of the relationship may be pertinent to claims of malpractice, informed consent, and even fraud, as well as to professional discipline. In these sorts of cases, materiality is closely related to the question of causation, roughly turning on whether the withheld information might have changed the decision of a reasonable advisee (i.e., a patient). The injured plaintiff will predictably testify that the information would have impacted his or her choice, but that self-serving testimony may be unreliable. The fact finder is left to speculate about the counterfactual world in which the information was disclosed.

This Article shows how randomized vignette-based experimentation may create a valuable form of evidence to address these questions, for both litigation and policymaking. To demonstrate this method and investigate conflicts of interest in healthcare in particular, we recruited 691 human subjects and asked them to imagine themselves as patients facing a choice about whether to undergo a cardiac stenting procedure recommended by a cardiologist. We manipulated the vignettes in a 2×3 between-subjects design, where we systematically varied the appropriateness of the proposed treatment, which was described in terms of patient risk without the procedure (low or high), and manipulated the type of disclosure provided by the physician (none, standard, or enhanced). We used physician ownership of the specialty hospital where the surgery would be performed as the conflict of interest, disclosed or not, and the "enhanced" disclosure included notice that such relationships have been associated with biases in prescribing behavior.

We found that the mock patients were significantly less likely to follow the cardiologist's recommendation of surgical implantation of a drug-eluting stent when he disclosed a financial conflict of interest, regardless of whether the disclosure was standard or enhanced. We also found that the mock patients were more likely to choose the treatment when they faced greater risk without it. We did not, however, find that the disclosure made patients more discerning about the appropriateness of the procedure.

We discuss the implications for law and policy. Mock patients seem likely to act upon such information, declining the low-value healthcare when conflicts are disclosed. This finding suggests that the information is material to such transactions, and that disclosures may be salutary for medical decisions. Arguably, therefore, physicians already have a duty under the common law to disclose the financial relationships they choose to accept. Other regulators and policymakers should recognize and clarify this duty, and courts should embrace this form of evidence. Methodologically, although this empirical approach has limits, it reduces speculation by fact finders and policymakers, by at least focusing their attention on the right questions.

I. INTRODUCTION

The law often attempts to regulate the flow of information in transactions, forcing disclosure from those with more information to those with less information. However, it simply is not feasible, nor desirable, to dump mountains of trivial

information on a consumer.[1] Instead, in these ubiquitous regulations, the 'materiality' of information is the key question, asked in a range of contexts, for example: the professional responsibility of lawyers; criminal perjury; failure to warn in products liability; and security fraud.[2] In this article, we focus on the context of healthcare and information about the physician's financial relationships as another exemplar of this disclosure dynamic. We argue for a more thoughtful and empirically based approach to determining materiality.[3]

What is material to a patient's decision about whether to accept healthcare recommended by her physician? The question is timely as physicians are increasingly taking on financial relationships with other healthcare providers[4] and accepting money from the drug and device industries,[5] thus structuring their practices so that they receive income not merely from providing advice to patients. One recent study found that about one-third of all MRIs performed in California were by physicians who referred patients to themselves, thus generating fees on both sides of the transaction.[6] An analysis of public data in Massachusetts showed that, in addition to their revenues from patients and health insurance companies, about a quarter of physicians were accepting side payments from the makers of drugs and devices.[7] In some medical specialties with particularly high-cost procedures, nearly two-thirds of physicians were taking money from industry on the side.[8]

There is a substantial body of literature indicating that professionals significantly alter their practice patterns when financial conflicts of interest are present, particularly when in the form of ownership in facilities where recommended

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[1] *See* Omar Ben-Shahar & Carl E. Schneider, *The Failure of Mandated Disclosure*, 159 U. PA. L. REV. 647, 687-89 (2011).

[2] *See*, *e.g.*, United States v. Gaudin, 515 U.S. 506, 509 (1995) (stating that, in the context of perjury, "[t]he statement must have 'a natural tendency to influence, or [be] capable of influencing, the decision of the decisionmaking body to which it was addressed.'") (citations omitted); Basic Inc. v. Levinson, 485 U.S. 224, 237 (1988) (discussing materiality in the securities fraud context); Wolfe v. McNeil-PPC, Inc., 773 F. Supp. 2d 561, 573 (E.D. Pa. 2011) (in the context of products liability, "[t]he rule applies only to misrepresentations of 'material facts' . . .") (citing RESTATEMENT (SECOND) OF TORTS § 402B (1979)); In re Conduct of Benett, 14 P.3d 66, 70 (Or. 2000) (explaining, in the context of lawyers' failure to disclose, "[a] material misrepresentation involves information that, if the decision-maker had known of it, would or could have influenced the decision-making process significantly.") (internal quotation marks omitted); David Monsma & Timothy Olson, *Muddling Through Counterfactual Materiality and Divergent Disclosure: The Necessary Search for a Duty to Disclose Material Non-Financial Information*, 26 STAN. ENVTL. L.J. 137, 165-66 (2007) (discussing materiality in the securities fraud context).

[3] *See e.g.*, Moore v. Regents of Univ. of Cal., 793 P.2d 479, 483 (Cal. 1990) (holding physicians must "disclose personal interests unrelated to the patient's health, whether research or economic, that may affect [their] professional judgment").

[4] *See* INST. OF MED., CONFLICT OF INTEREST IN MEDICAL RESEARCH, EDUCATION, AND PRACTICE 169-70 (Bernard Lo & Marilyn J. Field eds., 2009).

[5] *See* Jerome P. Kassirer, *Financial Conflict of Interest: An Unresolved Ethical Frontier*, 27 AM. J.L. & MED. 149, 159 ("Physicians have been conflicted about their dual roles as professionals and businessmen for millennia, but this dilemma has sharpened in recent decades . . . as involvement with industry has become an accepted norm."). For a discussion of the federal government's attempt to increase transparency of pharmaceutical company payments to physicians, see Peter Frost, *Feds to Publicize Drug Company Payments to Doctors*, CHI. TRIB., Sept. 26, 2014, http://www.chicagotribune.com/business/ct-sunshine-act-0928-biz--20140926-story.html#page=1. *See also* Peter Loftus, *Doctors Net Billions from Drug Firms*, WALL ST. J., Sept. 30, 2014, http://online.wsj.com/articles/u-s-agency-reveals-drug-makers-payments-to-doctors-1412100323.

[6] *See* Jean M. Mitchell, *The Prevalence of Physician Self-Referral Arrangements After Stark II: Evidence from Advanced Diagnostic Imaging*, 26 HEALTH AFF. 415, 422 (2007).

[7] Aaron S. Kesselheim et al., *Distributions of Industry Payments to Massachusetts Physicians*, 368 NEW ENG. J. MED. 2049, 2051 (2013).

[8] *Id*.

procedures would be conducted.[9] Particular attention has been given to the clinical practice and biomedical research settings in which various forms of financial incentives can skew physicians' advice and possibly lead to bad decisions by patients or research subjects.

The timeliness of these questions is illustrated by recent reports of profit-seeking physicians unnecessarily recommending percutaneous coronary intervention with stent placement, which have led to medical board actions, malpractice litigation, federal regulatory fines, and even criminal prosecutions.[10] Similarly illustrative is *Barton v. Tomecek*, an ongoing federal case in which the plaintiff alleges that his physician performed unnecessary surgery and failed to obtain consent because he failed to disclose an ownership interest in the hospital where the surgery was done[11]. Prior empirical research on this very same hospital showed that, after buying in, the new physician-owners dramatically changed their prescribing practices towards more intensive, higher-cost healthcare.[12]

Scholars have explored many approaches to dealing with conflicts of interest, ranging from outright bans on financial relationships to required disclosure of the conflicting interests, either passively on websites or directly to patients.[13] When and by whom a disclosure is made might influence outcomes, but the scientific literature is in its infancy.[14]

One motivation for utilizing disclosure is the imperative of informed consent. This doctrine has constitutional dimensions. It also has moral force, as it insists that patients are in the best position to make medical decisions in light of their own preferences once a physician supplies them with all pertinent information.[15]

Notably, there are two distinct reasons why informed consent might require disclosure of financial interests. The first reason is based on autonomy: such information is essential to the patient's informed decision.[16] The patient has a right

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[9] For a review of the literature, see Christopher Robertson et al., *Effect of Financial Relationships on the Behaviors of Health Care Professionals: A Review of the Evidence*, 40 J.L. MED. & ETHICS 452 (2012).

[10] *See* Heather O'Shea et al., *Continued Focus on Medical Necessity of Interventional Cardiology Procedures: Reactive and Proactive Strategies for Hospitals*, 22 BNA HEALTH L. REP. 1749 (2013); Daniel Lathrop, *North Texas Doctor Fined Over Unneeded Stent Implants*, DALLAS NEWS, Sept. 18, 2013, http://watchdogblog.dallasnews.com/2013/09/north-texas-doctor-fined-over-improper-stents.html/.

[11] Barton v. Tomecek, No. 11-CV-619-CVE-TLW, 2012 WL 3730066, at *1 (N.D. Okla. Aug 28, 2012).

[12] Jean M. Mitchell, *Do Financial Incentives Linked to Ownership of Specialty Hospitals Affect Physicians' Practice Patterns?,* 46 MED. CARE 732, 735-36 (2008).

[13] *See generally* Christopher Robertson, *Biased Advice*, 60 EMORY L.J. 653 (2011) (reviewing and testing various approaches to dealing with conflicts of interest). Federal anti-kickback laws are an example of a "ban strategy." *Id.* at 662; *see, e.g.*, OFFICE OF INSPECTOR GEN., DEP'T HEALTH AND HUMAN SERVS., SPECIAL FRAUD ALERT: PHYSICIAN-OWNED ENTITIES 2-3 (2013) ("[P]hysician owned entities that derive revenue from selling, or arranging for the sale of, implantable medical devices ordered by their physician-owners for use in procedures the physician-owners perform on their own patients at hospitals or ambulatory surgical centers" can violate the federal anti-kickback statute, Section 1128B(b) of the Social Security Act, even if physicians' financial conflicts are disclosed.).

[14] *See, e.g.*, Mark Hall et al., *How Disclosing HMO Physician Incentives Affects Trust*, 21 HEALTH AFF. 197, 200-02 (2002) (disclosing physicians' financial incentives via letter from health plan, followed by call from market research firm, does not negatively affect patients' trust in their physicians); George Loewenstein et al., *The Unintended Consequences of Conflict of Interest Disclosure*, 307 JAMA 669, 670 (2012) ("[D]isclosure works better when it is provided by third parties and when the patient is given time to reflect dispassionately on the advice (and the disclosure) and make his or her decisions while not in the presence of the physician.").

[15] RUTH FADEN ET AL., HISTORY AND THEORY OF INFORMED CONSENT 14 (1986).

[16] *Id.* at 308.

to know, and to withhold that information is to disrespect the patient's personhood.[17] The second reason is consequentialist: disclosures may improve the decisions patients make, and thus improve the outcomes patients experience.[18] The latter approach obviously depends on an empirical claim that the disclosure would impact the patient's behavior. Even the former approach, based on autonomy, may benefit from empirical investigation, as a way to operationalize the concept of "materiality."[19] If disclosures, when given, do in fact impact a significant proportion of the decisions made by patients; that strongly suggests that the information was important to those decisions. On the other hand, given the potential for information overload, it may not offend the personhood of a patient to withhold trivial information that is so very unlikely to have any impact on her decision.[20]

For legal liability to attach where a patient claimed that she gave invalid consent due to lack of some specific information, there are two primary questions. First, the law sets a standard for what a physician must disclose.[21] Second, the law sets a standard for what a plaintiff must show to establish causation for any injury.[22]

As to the scope of required disclosures, statutes and regulations impose some per se requirements. For example, a Hawaii statute requires that a physician disclose the patient's condition, the nature of the proposed treatment, anticipated results, recognized possible alternatives, and anticipated benefits and risks of the proposed treatment and alternatives.[23] Medicare statutes also require certain conflict of interest disclosures.[24] Beyond this domain of specified mandatory disclosures, jurisdictions vary—and are evolving—in how they state the standard for what is required. The underlying concept seems to turn on the notion of "materiality," which has been defined, roughly, as "what a prudent physician would or should realize a reasonable person in the shoes of the plaintiff would want to know when making a decision about her care."[25] The idea comes from a trio of cases decided in 1972—most famously *Canterbury v. Spence*—that rejected a physician-oriented standard for determining what patients must be told to conform to informed consent requirements.[26] A subjective standard could require disclosure of whatever facts

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[17] *Id.* at 4.

[18] *Id.* at 14.

[19] *See infra* Part IV(C).

[20] *See* KATHLEEN M. BOOZANG ET AL., CTR. FOR HEALTH & PHARM. LAW & POLICY, THE LIMITS OF DISCLOSURE AS A RESPONSE TO FINANCIAL CONFLICTS OF INTEREST IN CLINICAL RESEARCH 13 (2010) ("[E]vidence shows that information overload, particularly where it includes irrelevant or insignificant information, can cause decision-making that is worse than if the user had been provided less information or no information at all.").

[21] DAN DOBBS ET AL., THE LAW OF TORTS § 309 (2d ed. 2011).

[22] *Id.* § 311.

[23] HAW. REV. STAT. § 671-3(b) (2013).

[24] *See, e.g.*, 42 C.F.R. § 489.20(u) (2010) (requiring written notice of physician ownership interests at admission or at an out-patient visit and disclosure of such interests in writing upon referral). *See generally* Paula Tironi, *The "Stark" Reality: Is the Federal Physician Self-Referral Law Bad for the Health Care Industry?*, 19 ANNALS HEALTH L. 235 (2010) (discussing the exceptions and difficulties of the self-disclosure requirements of the Stark Act).

[25] *See* Canterbury v. Spence, 464 F.2d 772, 787 (D.C. Cir. 1972) (internal citation omitted) (stating that a risk is material "'when a reasonable person, in what the physician knows or should know to be the patient's position, would be likely to attach significance to the risk . . . in deciding whether or not to forego the proposed therapy.").

[26] *Id.*; Cobbs v. Grant, 502 P.2d 1, 11-12 (Cal. 1972) (citing *Canterbury* with approval); Wilkinson v. Vesey, 295 A.2d 676, 687 (R.I. 1972) ("The keystone of this doctrine is every competent adult's right to forego treatment, or even cure, if it entails what for him are intolerable consequences or risks however unwise his sense of values may be in the eyes of the medical profession, or even the community.").

were material to the patient/plaintiff, but these cases adopted an "objective reasonable person" standard to avoid requiring doctors to "guess" at what particular patients would want to know.[27]

The second essential component of a claim for breach of informed consent is causation. It is closely related to the materiality element.[28] The overwhelming majority rule is that the plaintiff must show some likelihood that the patient would have refused consent if the undisclosed material information had been disclosed.[29] There is some authority that adopts a subjective "this patient" causation standard, while other authority suggests a more objective notion of the "reasonable" patient in that situation. Courts often require, explicitly or implicitly, that the plaintiff must meet both tests.[30]

In litigation alleging a failure to disclose, courts often allow patients to testify regarding their own preferences for disclosure. The patient's preferences are dispositive under the subjective disclosure standard, but of course one worries that such self-serving testimony may be inaccurate, over-estimating the patient's ex ante desire for such information.[31] Survey methods, which ask hypothetical questions of a larger number of people, are thus arguably more objective, but likewise generally conclude that "many disclosure recipients want to know about [financial conflicts]."[32] Even when focused on the particular factual omission alleged in a given case, survey methods may underestimate or overestimate patient materiality.[33] Individuals are notoriously bad at estimating the factors that influence their own decisions.[34]

Thus, for both policymakers setting general requirements for disclosure ex ante and courts attempting to determine materiality ex post, empirical questions remain open. A 2013 "systematic literature review [sought] published research addressing

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[27] *Canterbury*, 464 F.2d at 787; *Cobbs,* 502 P.2d at 11-12 (citing *Canterbury* with approval, but only addressing the reasonable person in the context of causation); *Wilkinson*, 295 A.2d at 689.

[28] Similarly, scholars have noted that the reliance and causation elements are closely related, but serve distinct purposes. *See, e.g.*, John C. Goldberg et al., *The Place of Reliance in Fraud*, 48 ARIZ. L. REV. 1001 (2006).

[29] DAN DOBBS ET AL., *supra* note 21, § 311. Here, too, the physician stands in the shoes of the particular patient/plaintiff. *Id.* (citing Bernard v. Char, 903 P.2d 667 (Haw. 1995) and Ashe v. Radiation Oncology Assocs., 9 S.W.3d 119 (Tenn. 1999)).

[30] *Id.*

[31] *See* Jaime Staples King & Benjamin W. Moulton, *Rethinking Informed Consent: The Case for Shared Medical Decision-Making*, 32 AM. J.L. & MED. 429, 445 (2006).

[32] Adam Licurse et al., *The Impact of Disclosing Financial Ties in Research and Clinical Care: A Systematic Review,* 170 ARCHIVES INTERNAL MED. 675, 680 (2010).

[33] *See* King & Moulton, *supra* note 31, at 451-52.

[34] The literature on discrimination sheds light here. *See* Charles R. Lawrence III, *The Id, the Ego, and Equal Protection: Reckoning with Unconscious Racism*, 39 STAN. L. REV. 317, 324-44 (1987) (finding that people form racist beliefs unconsciously and are unaware of their discriminatory motives); Audrey J. Lee, *Unconscious Bias Theory in Employment Discrimination Litigation*, 40 HARV. C.R.-C.L. L. REV. 481, 483-88 (2005) (finding that the natural process of categorizing like objects together and related biases leads to stereotypes that create strong unconscious biases and preferences, especially in regard to race discrimination); Amy L. Wax, *The Discriminating Mind: Define It, Prove It*, 40 CONN. L. REV. 979 (2008) (observing the difficulty of determining whether institutional actors are motivated by unconscious biases towards race and sex in disparate outcome cases). *See also* Dan Simon, *A Third View of the Black Box: Cognitive Coherence in Legal Decision Making*, 71 U. CHI. L. REV. 511, 513 (2004) ("The research reveals an unconscious transformation of the way decisions are mentally represented, ultimately leading to a seemingly straightforward choice between a compelling alternative and a weak one."). For a discussion of heuristics and other impediments to understanding one's own preferences, and how to fit those preferences with choices, see Ben-Shahar & Schneider, *supra* note 1, at 704-42 (2011). *See generally* CARL SCHNEIDER, THE PRACTICE OF AUTONOMY: PATIENTS, DOCTORS, AND MEDICAL DECISIONS (1998).

the question, 'What is the evidence that disclosure of COIs in patient decision aids reduces biased decision making?'"[35] The reviewers found no direct evidence addressing that question.[36]

In other domains where disclosure may be required, empirical research has shed some light.[37] In healthcare, a recent review article highlights the need for research on the effects of disclosures of conflicts of interest.[38] In the article, Licurse draws from post-1987 studies with original, quantitative data meeting certain quality criteria.[39] There were only twenty eligible studies within 244 "potentially eligible abstracts," and the heterogeneity of even those twenty studies prevented quantitative synthesis.[40] Although seven studies addressed the impact of disclosure on willingness to participate in research, "[n]o studies assessed the impact of physician FT [financial ties] disclosure on patients' willingness to receive clinical care."[41] Strangely, although "patients and research participants largely want to know about physician and researcher FTs . . . fewer believed that disclosure would affect their decision-making."[42] Indeed, "no more than one-third of patients in any of the included studies reported reduced willingness to participate in research when FTs were disclosed."[43] Licurse's survey shows that, as of the date of his review, there was no authority directly addressing whether financial conflict of interest disclosures changed patients' decisions in the treatment setting (as distinct from a biomedical research setting).[44] The survey also reflects the conflicting claims regarding, and dearth of study concerning, the effect of disclosure on "compliance" or "trust"[45] in the clinical research context.[46]

A newer, unpublished working paper sheds some light. This vignette-based study provided mock patients with choices between healthcare recommended (or not) by a physician with or without conflicting interests.[47] The authors conclude: "Disclosure creates decreased trust and increased insinuation anxiety. Although decreased trust will lead to patients being less likely to take the doctor's

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[35] Michael J. Barry et al., *Disclosing Conflicts of Interest in Patient Decision Aids*, 13 BMC MED. INFORMATICS & DECISION MAKING, Nov. 29, 2013, at S3.

[36] *Id.*

[37] For a discussion of the impact of disclosing conflicts of interest in the financial advising, see, for example, Bryan K. Church & Xi (Jason) Kuang, *Conflicts of Interest, Disclosure, and (Costly) Sanctions: Experimental Evidence*, 38 J. LEGAL STUD. 505, 527 (2009).

[38] Licurse et al., *supra* note 32, at 681.

[39] *Id.* at 676.

[40] *Id.* at 676-77.

[41] *Id.* at 679. Perhaps the best study addressing the disclosure of financial interests in the research context is Kevin Weinfurt et al., *Effects of Disclosing Financial Interests on Participation in Medical Research: A Randomized Vignette Trial*, 156 AM. HEART J. 689 (2008). This study found that disclosure of equity interests in the company whose drug was being tested affected willingness to participate in research. Such equity interests are similar to the ownership interests addressed in our study.

[42] Licurse et al., *supra* note 32, at 679-80.

[43] *Id.* at 680.

[44] *Id.*

[45] "Trust" is an ambiguous term. Our study conceptualized trust as a patient's belief that the physician would make recommendations solely based on the patient's best interests. Although one can argue "best interests" is itself a vague term, this phrase focuses on the specific context of formulating recommendations. Trust encompasses many other concepts, for example, a patient's belief in the doctor's competence to perform a procedure. *See* Roy G. Spece, Jr., *Direct and Enhanced Disclosure of Researcher Financial Conflicts of Interest: The Role of Trust*, 23 HEALTH MATRIX 409, 417-18 (2013).

[46] Licurse et al., *supra* note 32, at 677.

[47] Sunitah Sah et al., *Insinuation Anxiety: Fear of Signaling Distrust After Conflict of Interest Disclosures* 8-9 (Dec. 11, 2011) (working paper), available at http://papers.ssrn.com/sol3/papers.cfm?abstract_id=1970961.

recommendation, increased insinuation anxiety created by disclosure increases the pressure to comply with the doctor's recommendation."[48] In a more recent study using a stylized decision task with small prizes for performance, Sunita Sah found that advisees who received a conflict of interest disclosure hewed *more closely* to the advice given. That is to say, a disclosure mandate backfired. This dynamic was not, however, observed in prior published laboratory experiments with similarly stylized decision-tasks. Thus, the literature on the impact of disclosure remains unsettled.

To investigate the potential for using randomized experiments as evidence in litigation and policymaking, and to explore whether and how patients will respond to physician disclosures of conflicting interests in physician self-referral situations in particular, we designed the following experiment. We hypothesized that patients may respond negatively to the disclosure by reducing the reliance they place on such advice. Such a finding would make the disclosure mandate salutary, at least when the conflicting interest is in fact likely to bias the physician's advice, and would in any case make the disclosure arguably "material" as a matter of legal liability. We further hypothesized that patients might be particularly likely to do so in settings where the treatment was less appropriate.

II. METHODS

A. PARTICIPANTS

We recruited human subjects from an online pool of workers called Amazon Mechanical Turk,[49] with an advertisement to participate in an approximately ten-minute research experiment in exchange for $0.75 payment. The final study population ($N = 691$) was predominantly white (81%), tended to be male (63%), and was about thirty years old. [50] A demographics table is located in the Appendix.

B. DESIGN AND STIMULI

Participants were instructed to imagine themselves as patients within the vignette (hereinafter "mock patients"). We consulted with three physicians, including a cardiology specialist, to construct a realistic vignette, in which a patient would be tasked with making a difficult healthcare choice, and the physician would often have conflicting interests. All vignettes contained the same core scenario: a variety of symptoms indicative of coronary heart disease (e.g., chest pains, elevated cholesterol, and arteriographic evidence of coronary artery blockage); the notable possibility of a future heart attack; a treatment choice between either oral drug

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[48] *Id.* at 32.

[49] *See generally* Adam J. Berinsky et al., *Evaluating Online Labor Markets for Experimental Research: Amazon.com's Mechanical Turk*, 20 POL. ANALYSIS 351 (2012) (assessing the recruitment process and subject diversification of Amazon Mechanical Turk); Gabriele Paolacci et al., *Running Experiments on Amazon Mechanical Turk*, 5 JUDGMENT & DECISION MAKING 411 (2010) (providing an overview of Amazon Mechanical Turk and the demographic composition of its users relative to other online and offline sources).

[50] Seven hundred and seventy-two persons proceeded past the informed consent page, although eighty-one cases (10%) were removed from analyses for one or more of three quality-assurance reasons: (1) failure to complete the task; (2) entry of "garbage" text (for example, smashed keys or copied-and-pasted question prompts); or (3) completing the experiment in less than three minutes or more than fourteen minutes, defined by visual inspection of a histogram, which suggested outliers who may not have attended to the task. All of these data-cleaning screens were performed prior to assessing the primary dependent variables.

therapy or implantation of a stent (a procedure known as percutaneous coronary intervention with drug-eluting stent, or "PCI"); and the recommendation of the cardiologist, which was always to implant the stent (i.e., undergo PCI).

More than a million cardiac stents are implanted each year, including some after a first heart attack—the FDA approved use—but also frequently in this setting, as a prophylactic prior to the first heart attack.[51] Stents have not, however, been proven effective for this purpose, and a large randomized, controlled trial demonstrated that patients who received stents prophylactically would have fared just as well on a much cheaper (and safer) regimen of drugs.[52] Mock patients were not provided with such a review of the literature, but instead were simply given the physician's advice, as may be typical in real world clinical settings.

We randomly assigned subjects to a 2×3 between-subjects design, wherein participants were exposed to one of six medical vignettes. The vignettes were systematically varied by level of patient risk (low or high), which impacted the appropriateness of the proposed treatment, and the type of disclosure provided by the physician (none, standard, or enhanced). Patient risk—and thus the appropriateness of the procedure—was manipulated by altering the number of coronary arteries with blockage from one to two and, ultimately, increasing the likelihood of a future heart attack within ten years; the likelihood was 10% or 20%, respectively, in the low- or high-risk conditions.[53]

Type of disclosure was manipulated by altering whether the cardiologist disclosed a conflict of interest—in particular, that he had an ownership interest in the hospital—and, if so, the nature of that disclosure. In the "none" condition, the cardiologist made no disclosure whatsoever, and the vignette simply ended after his recommendation to undergo PCI, without any mention of his financial interest in the procedure. In the "standard" disclosure condition, on the other hand, the following was appended after the recommendation:

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[51] *See* Ezekiel J. Emanuel & Jeffrey B. Liebman, Op-Ed., *Cut Medicare, Help Patients*, N.Y. TIMES, Aug. 23, 2011, at A25 (describing inefficiencies in health care spending and the prophylactic use of stents in particular). The average cost of a stent procedure can vary from $30,000 to $100,000, and thus is a significant driver of healthcare costs. *See* David Rosenfeld, *Is American Medicine Too Stent Happy?*, PAC. STANDARD (Apr. 17, 2010), http://psmag.com/health/is-american-medicine-too- stent-happy-12861.

[52] William E. Boden et al., *Optimal Medical Therapy with or Without PCI for Stable Coronary Disease*, 356 NEW ENG. J. MED. 1503, 1509-11 (2007) (randomized controlled trial); *see also* Htut K. Win et al., *Clinical Outcomes and Stent Thrombosis Following Off-Label Use of Drug-Eluting Stents*, 297 JAMA 2001, 2004 (2007) (finding that, of the 3323 patients enrolled in the study who had received stents, 54.7% had at least one off-label characteristic, meaning that the efficacy of the stent in that setting had not been proven to the FDA but may have been based on other scientific data).

[53] Although PCI is arguably not appropriate for any of these patients (as a prophylactic to a future heart attack), our physician consultant advised that the higher estimate of risk for the latter set of patients made it more appropriate clinically. Interview with Joseph Alpert, Professor of Med., and former Head of the Dep't of Med., Univ. of Ariz. Coll. of Med. (May 6, 2013). *See also* Giulio Stefanini & David R. Holmes, Jr., *Drug-Eluting Coronary-Artery Stents*, 368 NEW ENGL. J. MED. 254, 260 tbl.3 (2013). *See generally* Paul Chan et al., *Appropriateness of Percutaneous Coronary Intervention*, 306 JAMA 53 (2011) (finding that nearly all acute PCIs were appropriate in a "large contemporary US cohort"); David Morrow & William Boden, *Stable Ischemic Heart Disease*, *in* BRAUNWALD'S HEART DISEASE: A TEXTBOOK OF CARDIOVASCULAR MEDICINE 1210, 1258-69, 1290-99 (Robert Bonow et al. eds., 9th ed. 2010) (outlining American College of Cardiology [ACC]/American Heart Association [AHA] Guidelines for an array of diagnostic and therapeutic interventions); Manesh R. Patel et al., *ACCF/SCAI/STS/AATS/AHA/ASNC 2009 Appropriateness Criteria for Coronary Revascularization*, 53 J. AM. C. CARDIOLOGY 530 (2009) (finding that "the use of coronary revascularization for patients with acute coronary syndromes and combinations of significant symptoms and/or ischemia was viewed favorably [by a panel of several specialty and subspecialty societies]").

> I must inform you that I have an ownership interest in the hospital where I would do your procedure. So, if you choose the PCI procedure, I will not only be paid a fee for the procedure itself, but I will also receive a portion of the profits that the hospital earns as a result of the PCI treatment.

The "enhanced" disclosure contained the identical disclosure as in the "standard" disclosure condition, but also added the following information: "Some published studies claim that physicians are more likely to prescribe expensive and invasive procedures if they have an ownership interest in the hospitals where the recommended procedures will be done. The claimed increased likelihood is anywhere from two to sixty-five times more likely."

C. PROCEDURE AND MEASURED VARIABLES

Participants completed the experiment online, via a survey programmed and hosted on Qualtrics. The basic survey flow entailed an initial informed consent page, followed by a demographics questionnaire, and then the experiment itself: participants read one of the six medical vignettes, and then answered a series of questions about how they would behave and feel if actually experiencing the scenario.

The primary dependent variable of interest, answered immediately after the vignette, was a binary response (drug therapy or PCI) to the question, "Which course of treatment do you want to select?" A follow-up question prompted participants to explain their choice briefly, but in no fewer than 120 characters.

Further questions probed issues of choice confidence, perceived comprehension of treatment options, and physician trust. Specifically, participants were asked to assess the following: "How confident are you in your treatment choice?" ("not at all confident" to "absolutely confident"); "The cardiologist has only my interests in mind in making his recommendation" ("strongly disagree" to "strongly agree"); "How likely would you be to get a second opinion from another cardiologist before finalizing your decision?" ("very unlikely" to "very likely"); and "I fully understand the treatment choices presented to me by the cardiologist" ("strongly disagree" to "strongly agree"). [54]

The survey concluded with a debriefing page, which asked participants whether they encountered any computer or other problems, whether they had any additional thoughts or comments, and what they believed was the purpose of the study. These debriefing questions were primarily used for quality-assurance purposes, and will not be further reported below.

III. RESULTS

A. TREATMENT CHOICE

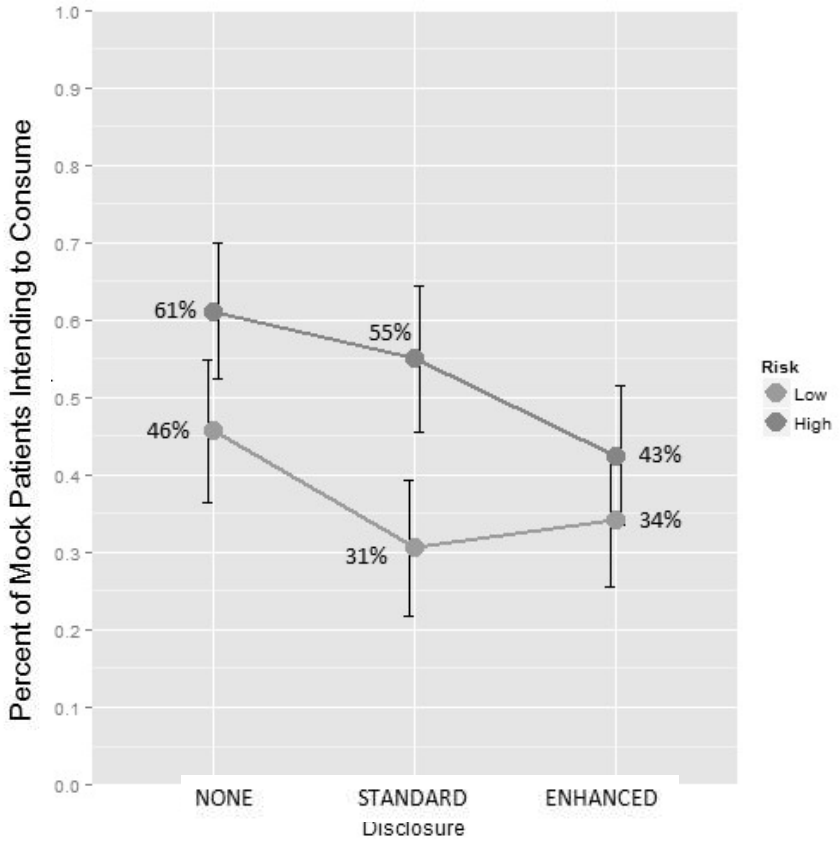
We used the statistical software R for computing proportions and logistic regressions, and for plotting the figures shown below. Examination of the treatment choice proportions[55] reveals a pattern largely coinciding with predicted effects:

[54] Response modality was a seven-point Likert scale for each, but with the particular anchors in parentheses.

[55] *See infra* Figure 1.

mock patients were less likely to choose the cardiologist's recommended treatment of surgical implantation of a drug-eluting stent (i.e., PCI) when he disclosed a financial conflict of interest in prescribing that treatment. Comparing the "none" and "standard" disclosure conditions, the percentage opting for PCI dropped 15% (from 46% to 31%) in the low-risk condition and 6% (from 61% to 55%) in the high-risk condition, when the cardiologist disclosed that he would "receive a portion of the profits that the hospital earns as a result of the PCI treatment." A further 12% drop (from 55% to 43%) was observed in the high-risk condition when the "enhanced" disclosure, wherein the cardiologist referenced published research indicating he was "two to sixty-five times more likely" to prescribe PCI due to his conflict of interest, was used. However, we found no such enhanced effect in the low-risk condition, where the rate of PCI uptake remained about the same for the standard and enhanced disclosures (31% versus 34%). Across all types of disclosure, mock patients were more likely to select PCI when at high-risk.

Figure 1. Portion of mock patients choosing the surgical stent treatment (PCI), the medically inferior treatment[56] for which the cardiologist had a conflict of interest, as a function of perceived risk to patient who foregoes procedure and type of disclosure given by physician. As shown by logistic regressions, disclosures reduced intention to consume treatment and mock patients were less likely to consume when they faced lower risk without treatment. However, a significant interaction was not observed.



[56] *See supra* note 53 and accompanying text.

Table 1. Logistic regressions predicting mock patient's intent to consume surgical stent, displaying coefficients with standard errors in parenthesis.

º $p < 0.10$, * $p < 0.05$, ** $p < 0.01$, *** $p < 0.001$

	Model 1	**Model 2**	**Model 3**
	ß (S.E.)	ß (S.E.)	ß (S.E.)
Intercept	-0.19 (.15)	-0.17 (0.19)	-0.01 (.33)
Risk_High	0.66 (.16) **	0.63 (.26) *	0.66 (0.16) ***
Disclosure_Standard	-0.44 (.19) *	-0.65 (0.28) *	-0.42 (0.19) *
Disclosure_Enhanced	-0.63 (.19) ***	-0.48 (0.27) º	-0.67 (0.19) ***
Risk_High × Disclosure_Standard	-	0.40 (0.39)	-
Rish_High × Disclosure_Enhanced	-	-0.27 (0.38)	-
Male	-	-	0.45 (0.17) **
Minority	-	-	-0.27 (0.21)
College	-	-	0.51 (0.60)
Age_10	-	-	-0.12 (0.08)
Income			-0.01 (0.02)

Table 2. Means (and standard deviations) of mock patient confidence in treatment choice, perceived understanding of the treatment options, likelihood of seeking a second opinion from another cardiologist, and agreement with the statement "the cardiologist has only my interests in mind in making his recommendation." All responses are on a 1-7 point Likert scale, with higher numbers indicating greater confidence, higher likelihood of seeking a second opinion, etc. Significant differences include: (a) trust is lower when a disclosure is made ($F(2,685) = 52.31$, $p < .0001$); (b) disclosure increased intentions to obtain a second opinion ($F(2, 685) = 4.13$, $p = .02$); and (c) self-perceived understanding decreases with higher levels of disclosure in the low-risk condition, yet increases with higher levels of disclosure in the high-risk condition ($F(2, 685) = 3.69$, $p = .03$).

Risk	*Disclosure*	Confidence in Choice	Self-Rated Understanding	Desire for Second Opinion	Trust in Physician
Low	None	4.47 (1.04)	5.10 (0.74)	4.70 (1.11)	4.40 (1.00)
	Standard	4.45 (1.16)	5.06 (0.92)	4.70 (1.31)	3.25 (1.44)
	Enhanced	4.37 (1.08)	4.80 (0.99)	4.96 (1.06)	3.44 (1.25)
High	None	4.29 (1.11)	5.02 (0.84)	4.55 (1.16)	4.57 (0.98)
	Standard	4.37 (1.06)	5.05 (0.32)	4.75 (1.20)	3.70 (1.13)
	Enhanced	4.30 (1.03)	5.12 (0.83)	4.90 (1.10)	3.61 (1.24)

Binary logistic regression was used to assess the statistical significance of the above proportions, including a possible disclosure by risk interaction, and also to provide further control (beyond randomization) of demographic covariates. Table 1 displays the results of three regression models. The first model regressed treatment choice (0 = drug; 1 = PCI) on the independent variables using dummy coding: Risk_High (0 = low risk; 1 = high risk); Disclosure Standard (0 = none; 1 = standard disclosure); and Disclosure_Enhanced (0 = none; 1 = enhanced disclosure). The second model builds upon the first model by adding the possible risk by disclosure interaction terms. The third model includes demographic covariates of Male (0 = female; 1 = male), Minority (0 = white; 1 = non-white), College (0 = less than Bachelor's degree; 1 = Bachelor's degree or higher), and Age_10 (age at ten-year intervals); since the interaction terms were non-significant even with demographic covariates and their inclusion complicates interpretation of the other coefficients, the third model does not include them.

The statistical results confirmed the main effects of both patient risk and type of disclosure on treatment choice. Referring to the third model (in Table 1), mock patients were about twice as likely to choose a surgical stent over oral drug therapy when suffering a high rather than low risk of future heart attack (odds ratio = 1.93; 95% CI = 1.41 – 2.64; $p < 0.0001$). More importantly for purposes of this study, a Wald test confirms an overall effect of disclosure type ($\chi 2$ (2) = 12.6, $p = 0.002$), with model coefficients for the two disclosure dummy variables estimating that PCI was about half as likely to be chosen, relative to the "none" disclosure condition, when either a "standard" (odds ratio = 0.65; 95% CI = 0.44 – 0.95; $p = 0.03$) or "enhanced" (odds ratio = 0.51; 95% CI = 0.35 – 0.74; $p < 0.001$) disclosure was made. However, a Wald test comparing the coefficients for Disclosure_Standard and Disclosure_Enhanced fails to reject the null hypothesis that "standard" and "enhanced" disclosures have the same effect ($\chi 2$ (1) = 1.6, $p = 0.21$). Disclosure, therefore, significantly reduced the odds that a mock patient heeded the doctor's (conflicted) recommendation, but that reduction was the same regardless of whether mock patients faced a "standard" or "enhanced" disclosure.

The proportions suggest a possible interaction effect; namely, that enhanced disclosure may have a stronger effect, but only in the patient high-risk patient scenario.[57] The coefficients for the interaction terms of patient risk by type of disclosure, found in the second model (see Table 2), fail to find a significant interaction of patient risk in the comparisons of "none" versus "standard" disclosure as well as "none" versus "enhanced" disclosure. However, a Wald test comparing the coefficients for the two interaction terms is trending toward traditional significance ($\chi 2$ (1) = 2.9, $p = 0.08$), suggesting—cautiously—that an enhanced disclosure might have stronger effect (relative to standard disclosure) in at least some circumstances.

B. CONFIDENCE AND PERCEIVED UNDERSTANDING

Table 2 summarizes the means and standard deviations of the Likert scale responses to the follow-up questions. Analysis of Variance (ANOVA) was used to assess whether any main effects of patient risk or type of disclosure, or the interaction of the two, were statistically significant.

[57] *See supra* Table 1, and note how the proportion of mock patients choosing PCI have a steep drop from 46% to about 31% in the low-risk condition, but a more gradual, linear reduction from 61% to 55% to 43% in the high-risk condition.

Confidence in making a good treatment choice was not significantly affected by patient risk ($F(1685) = 1.92$, $p = 0.17$) or type of disclosure ($F(2685) = 0.29$, $p = 0.75$), and no interaction was found ($F(2685) = 0.20$, $p = 0.82$). Rather, across all six conditions, participants reported being "confident" to "very confident" in their treatment decisions. Self-perceived understanding of the treatment options was likewise unaffected by either patient risk ($F(1685) = 1.40$, $p = 0.24$) or type of disclosure ($F(2685) = 0.92$, $p = 0.40$). There was, however, a significant interaction effect ($F(2685) = 3.69$, $p = 0.03$). The interactive trend is clear in the reported means: self-perceived understanding *decreases* with higher levels of disclosure in the low-risk condition, yet *increases* with higher levels of disclosure in the high-risk condition. Nonetheless, all response means hover near five ("agree"), with only the low-risk, enhanced disclosure condition exhibiting a high four ("somewhat agree") mean rating.[58]

C. PURSUIT OF A SECOND OPINION

Type of disclosure had a significant main effect on intentions to obtain a second opinion from another cardiologist ($F(2685) = 4.13$, $p = 0.02$). In particular, participants were more likely to seek a second opinion if the physician disclosed a conflict of interest. Post hoc analysis (Tukey Honest Significant Differences) revealed insignificant differences between "none" and "standard" disclosure conditions ($p = 0.63$) as well as "standard" versus "enhanced" disclosure conditions ($p = 0.16$), but a significant difference between "none" and "enhanced" disclosure conditions ($p = 0.01$). In other words, mock patients were more likely to seek a second opinion (relative to "none" disclosure) if they received an "enhanced" disclosure, but not if they only received a "standard" disclosure. This is most clear in the low-risk condition, where the mean intention was a 4.70 in both the "none" and "standard" conditions, but rose to 4.96 in the "enhanced" condition.[59] In the high-risk condition, on the other hand, there is a more linear increase, from 4.55, to 4.75, to 4.90.[60]

D. TRUST IN PHYSICIAN

Agreement with the statement, "the cardiologist has only my interests in mind in making his recommendation"—an operationalization of the concept of trust—was significantly affected by both patient risk and type of disclosure. In particular, trust was lower in the low-risk condition than in the high-risk condition ($F(1685) = 8.39$, $p < 0.01$) , and trust is lower when a disclosure was made ($F(2685) = 52.31$, $p < .0001$). Regarding the latter, post hoc analysis (Tukey Honest Significant Differences) revealed significant differences between the "none" and "standard" disclosure conditions ($p < 0.001$) as well as the "none" versus "enhanced" disclosure conditions ($p < 0.001$), but a non-significant difference between "standard" and "enhanced" disclosure conditions ($p = 0.01$). This suggests that disclosure reduces trust relative to no disclosure, but about equally so for disclosure of either the "standard" or "enhanced" variety. On the other hand, examining the mean ratings reveals a now familiar trend: in the low-risk condition, trust exhibits a large step

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[58] *See supra* Table 2.

[59] *Id.*

[60] Note the similarity of this result to the non-significant, but trending, interaction that was found for the effects on treatment choice.

drop when a disclosure is made (from 4.40 in the "none" condition, to similar ratings of 3.25 and 3.44 in the "standard" and "enhanced" conditions, respectively), but drops more linearly in the high-risk scenario (from 4.57 to 3.70 to 3.61).[61] Nonetheless, no significant interaction was found ($F(2685) = 0.97$, $p = 0.38$).[62]

IV. DISCUSSION

In this section we will discuss the limitations of our study and some of the legal, policy, and moral implications of our findings.

A. LIMITATIONS

A primary limitation of any laboratory vignette-based experiment is that it may lack ecological validity.[63] Our respondents were not sick people sitting in physician's offices, scared for their own lives. Our mock patients also made a choice in a relatively limited amount of time, while patients in the real world have an opportunity to ask questions, do research, or deliberate about their choices, either alone or with friends or family. A more robust field experiment that avoids these limitations may or may not be feasible or ethical.

Relatedly, our study population is not representative of any particular pool of future patients. Although more diverse than the student-based research pools available on university campuses, the online population underrepresents some demographic profiles and fails to represent certain subsets, such as the elderly, altogether.[64] Randomization and multivariate regressions are of some value, but cannot be substitutes for future work. Still, we found that an important subset of the American population responds in a salutary way to disclosures. For the reasons explained below, that finding may have legal and policy salience, regardless of whether other demographic groups may tend to respond somewhat differently.

Another limitation of our study is that there was no direct contact between advisors and advisees, which could significantly change the social norms and other dynamics of the situation. One possible strength of the "lottery" design used in one of Sah's studies discussed above is such patient-to-physician contact, but a benefit of vignette studies is that they place the respondents in a realistic treatment choice setting in which the risk is to health rather than loss of small rewards such as candy bars.[65]

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[61] *See supra* Table 2.

[62] A study in which disclosures were made by the insurers (with follow-up by calls from a market research firm) reports that "[d]isclosing the positive and negative features of incentives and increasing knowledge of these incentives does not, in the short term, reduce trust in physicians or insurers and may have a mild positive impact on physician trust, perhaps as a consequence of displaying candor and increasing understanding of positive features." Hall et al., *supra* note 14, at 197. *See also* Weinfurt et al., *supra* note 41, at 694 (concluding that "[a]lthough disclosure of investigators' financial interests in research does not substantially affect willingness to participate, potential research participants attach some importance to this information, and they are more troubled by equity interests than by per capita payments that cover the costs of research").

[63] *See* John W. Peabody et al., *Comparison of Vignettes, Standardized Patients, and Chart Abstraction: A Prospective Validation Study of 3 Methods for Measuring Quality*, 283 JAMA 1715, 1721 (2000).

[64] Samuel D. Gosling et al., *Should We Trust Web-Based Studies? A Comparative Analysis of Six Preconceptions About Internet Questionnaires*, 59 AM. PSYCHOLOGIST 93, 98-99 (2004).

[65] *See* Sunitah Sah et al., *The Burden of Disclosure: Increased Compliance with Distrusted Advice*, 104 J. PERSONALITY & SOC. PSYCHOL. 289, 296 (2013) (finding that advisees are more likely to comply with advice given directly by advisers than by third parties).

Still another limitation of our study is that it did not allow us to determine whether the disclosure objectively *improved* the patient's decisions, rather than merely *changed* their decisions. One could read the biomedical science literature to conclude that, given the facts stipulated in the scenario, patients were better off declining the physician's advice for a stent, making the disclosure salutary.[66] However, some learned physicians would disagree, and defend such prescriptions on the merits.[67] We plan a future study with vignettes that involve choices between a clearly negligent physician recommendation and an alternative consistent with best practices.

Another limitation of our study is that it addressed only the effects of a severe conflict of interest in the form of ownership interests.[68] It therefore cannot speak directly to either the effects of other forms of financial conflicts, such as managed care incentives to encourage frugal practice patterns, or to situations where incentives toward frugal care accompany possible offsetting incentives, such as rewards for delivering quality care.[69] Patients may respond differently to disclosures in those domains.

B. PRIMARY FINDINGS

While acknowledging the limitations, we now turn to some implications of our findings. First, our primary focus concerned the effect of disclosure and enhanced disclosure on patient acceptance of physician recommendations. Disclosure and enhanced disclosure significantly and substantially increased the probability that the mock patient would reject the conflicted physician's recommendations. There was no statistically significant difference in mock patient behavior when comparing standard disclosure to enhanced disclosure, and so it seems it is the existence of disclosure, as opposed to the strength of the disclosure, that sways mock patients.

Second, our findings shed some light on why the mock patients rejected physician recommendations. Disclosure and enhanced disclosure significantly and substantially increased the probability of patients not believing that their physicians have solely the patients' best interest in mind when making recommendations. This form of loss of trust might well explain why the patients rejected physician recommendations.

Third, our findings relate to how patients' psychological state or satisfaction may change when and after making treatment choices. Patients' confidence in their decisions and understanding of physician disclosures did not vary in a statistically significant manner with the degree of risk or the fact or level of disclosure. These findings contradict prior commentators' contentions that disclosure of conflicts is likely to confuse and demoralize patients.[70]

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[66] *See supra* note 51.

[67] *See supra* note 53 and accompanying text.

[68] *See* Hall et al., *supra* note 14, at 205 (discussing the limitations of the authors' study).

[69] For a survey field study of HMO financial incentive disclosure outside the context of specific treatment choices, see *id.*

[70] *See* BOOZANG ET AL., *supra* note 20, at 13-14 (2010) (concluding that financial conflict of interest "should not be incorporated into the informed consent process"); Jay R. Lieberman et al., *Disclosure of Financial Conflicts of Interest: An Evaluation of Orthopaedic Surgery Patients' Understanding*, 471 CLINICAL ORTHOPAEDICS RELATED RES. 472 (2013) (finding poor patient comprehension of disclosed financial conflicts of interest).

C. PROFESSIONAL RESPONSIBILITY AND LEGAL LIABILITY OF PHYSICIANS

Federal and state statutes, regulations, and common law opinions govern information transfer from physicians to patients.[71] The findings here might inform whether and how lawmakers should interpret, alter, or add to these disclosure or informed consent mandates. In particular, one might argue that, since a substantial portion of patients appears likely to behave differently once given such information, the information is thus material to their decisions.[72] Thus, such mandates should be interpreted, altered, and supplemented to favor their disclosure whenever feasible and in the absence of strong proof that disclosure would harm patients in the particular setting.

We found that disclosure of a conflicting interest reduced intent to consume by about one-fourth, which suggests that for a substantial number of patients the disclosure would be material information that would impact their clinical decision. These procedures pose very serious risks, including death and paralysis,[73] and non-disclosure of a conflicting interest seems to increase the likelihood that patients will consent to treatment and will thereby be exposed to those risks, along with any therapeutic benefits that the physician predicts. Our findings, paired with prior research suggesting that conflicting interests bias physician recommendations—presumably causing physicians to overestimate benefits and underestimate risks—suggest that disclosure of potent financial conflicts of interest arguably should be *added to* the list of presumptively required disclosures or *interpreted as* falling within the existing category of "risks" that presumptively must be required.

It can be answered that further research might show that patients have an irrational tendency to reject physician advice—throwing out the baby with the bathwater—when such disclosures are made; if so, such information perhaps should not be found material. Similarly, it might also be suggested that the decrease in "trust" that we found could work to the patient's detriment by negating a possible therapeutic effect of a good physician-patient relationship. If established, these would be policy reasons cutting against presumptively requiring that this information be disclosed. On the other hand, one can argue that even if such problems were established, they would be remedied by our finding that patients have an increased propensity to seek second opinions when conflict disclosures are made.[74] It can also be argued that decreased trust might be a good, in any event, because it might alert patients to be very careful when deciding whether to accept physicians' conflicted recommendations without a second opinion or research and consultation with family or friends.[75]

One approach to a possible problem of conflict disclosure leading to rejection of good recommendations—and another topic for further research—is allowing certain

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[71] *See supra* Part I.

[72] One would have to further argue that what a substantial portion of patients find important is also reasonable. *See Canterbury*, 464 F.2d at 787.

[73] *See* Steven C. Ajluni et al., *Perforations After Percutaneous Coronary Interventions: Clinical, Angiographic, and Therapeutic Observations,* 32 CATHETERIZATION CARDIOVASCULAR DIAGNOSIS 206, 209-10 (1994).

[74] *See* discussion *supra* Part III(C).

[75] *See generally* Brahmajee K. Nallamothu & Harlan M. Krumholz, Commentary, *Putting Ad Hoc PCI on Pause*, 304 JAMA 2059, 2059-60 (2010) (suggesting that due to financial incentives of doctors, ad hoc PCI operations should be paused for second opinions and consultation of friends and family).

"safe harbors" in which disclosure need not be made.[76] For example, if there are consensus guidelines that clearly support the conflicted physicians' recommendations, disclosure might not be required.[77] An argument against such an approach is that guidelines are general, while each patient is entitled to individualized consideration.[78] Accepted therapy is not necessarily required therapy.[79] Another way to offset possible overreaction to conflicts of interest may be to require the disclosure with an admonition that the patient should consider a second opinion or conduct research and give the ultimate decision extended deliberation.[80] Prior laboratory research has shown that such an approach may be promising for improving patient outcomes.[81]

One may cogently argue that there should be a presumption in favor of disclosure based on the moral and legal imperative of informed consent.[82] The presumption should be especially strong if patients state that they want the disputed information, and appear likely to act upon it.

D. A METHOD FOR PRODUCING EVIDENCE IN LITIGATION

Our research has revealed no instances in which courts have used these sorts of randomized experiments as evidence to inform the legal question of whether an advisor's withheld information was material to a plaintiff's choice. Instead, when deciding the issue of materiality as opposed to causation, courts have relied upon the perhaps self-serving testimony of plaintiffs, to say after the fact that they would have perhaps decided differently if they had known about their advisor's conflicting interest.[83]

Our randomized, between-subject design avoids these sorts of problems by isolating the question of whether exposure to disclosure changes the patient's likelihood of consuming, and providing an estimate as to what might have happened in the counterfactual situation where the disclosure was given. As we note in the

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[76] *Cf.*, 42 U.S.C. § 1395nn (2010); 42 C.F.R. § 1001.952 (2013) (creating safe harbors for physicians regarding conflicts of interest with regard to federal Medicare anti-kickback regulation).

[77] *See generally* INST. OF MED., *supra* note 4, at 176-88 (surveying the procedures with regard to disclosure of conflicts of interest by various organizations in healthcare).

[78] *See, e.g.*, Scott v. Bradford, 606 P.2d 554, 558 (Okla. 1979) (citing Wilkinson v. Vesey, 295 A.2d 676 (R.I. 1972)) ("A patient's right to make up his mind whether to undergo treatment should not be left to the local medical group. What is reasonable disclosure in one instance may not be reasonable in another.").

[79] *See* Nallamothu & Krumholz, *supra* note 75, at 2059 (suggesting that PCI may not be medically necessary as other options perform similarly or better in the long run for certain patient types).

[80] *See, e.g.,* ARIZ. RULES OF PROF'L CONDUCT, E.R. 1.8 (2003) ("A lawyer shall not enter into a business transaction with a client . . . unless . . . [among other requirements] the client is advised in writing of the desirability of seeking and is given a reasonable opportunity to seek the advice of independent legal counsel on the transaction . . . .").

[81] Robertson, *supra* note 13., at 653, 690-91 (testing a second opinion given after disclosed conflicted advice, and concluding that "the evidence shows that a disclosure mandate improves layperson performance when unbiased advisors are also available").

[82] *See, e.g.*, Robert Gatter, *Walking the Talk of Trust in Human Subjects Research: The Challenge of Regulating Financial Conflicts of Interest*, 52 EMORY L.J. 327, 355 (2003) (discussing the importance of disclosure of financial conflicts of interest in allowing individuals to preserve their bodily autonomy and to empower individuals to protects themselves from risk associated with the conflict of interest).

[83] *Moore*, 793 P.2d at 485-86.

"limitations" section above, a step of inference is required from our results with mock patients in order to make predictions about how real patients will behave.[84]

One particular step of inference is from the clinical vignette we utilized here and the decision that any particular patient faces. The sizeable but not overwhelming effects that we observed suggest that there may be some cases in which the disclosure makes no difference (and thus is arguably immaterial), and other cases in which the disclosure is impactful (and thus arguably material). In the "easiest" cases, no reasonable patient would decline the healthcare, regardless of the physician's conflict. In the "hardest" cases, the patient will be near equipoise, and the slightest indication that the physician may have ulterior motives will tip the patient towards declining the healthcare. This natural variation may deter policymakers from making per se rules requiring mandatory disclosures or banning certain financial relationships altogether, and instead retain a more general standard about materiality.

Thus, we suggest that litigants consider using these experimental methods to shed light on the question of materiality in real cases, including healthcare cases but also wherever materiality is in question.[85] Such an experiment would be conducted by an expert witness who is properly qualified for this sort of scientific endeavor.[86] Ideally, the expert should work from behind a "blind" that prevents him or her from designing or analyzing the experiment in a way that biases the outcome in favor of either side.[87]

The expert witness should customize the experimental vignette to reflect the facts of the case, including the particular treatments proposed. The expert will have to make the vignette detailed and complex enough that it reflects the reality of the decision facing the patient. The risk is that a superficial description of the clinical choice may have the effect of giving too much emphasis to the disclosure. We consulted with a physician to produce the vignette here, and such efforts will likely be routinely required. Most litigation in these sorts of cases will include subject-matter experts, and they could provide such input.[88]

There are multiple potential populations of mock patients that could be recruited, ranging from an inexpensive online convenience sample like we used here to a demographically valid survey. Alternatively, the expert could focus more precisely on a population that reflects the demographic profile of the plaintiff (e.g., age, race, gender, income). Such precision will have value only to the extent that there are reasons to believe that the sensitivity to disclosures is correlated with those demographics.

If produced in robust experiments, such data would present prima facie evidence about how real patients will behave.[89] While the limits to this sort of research should be carefully probed in cross-examination, this sort of data is likely more probative than judicial speculation, opinion surveys, or self-serving testimony of litigants. Randomized experimentation is thus a promising reform.

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[84] *See supra* Part IV(A).

[85] *See supra* note 2 and accompanying text.

[86] *See* FED. R. EVID. 702 (setting criteria establishing a qualified expert witness).

[87] *See* Christopher Tarver Robertson, *Blind Expertise*, 85 N.Y.U. L. REV. 174, 205 (2010) (describing the benefits of double-blind research experiments in preventing an impact from researchers' biases).

[88] Experimental data requires expert testimony. *See* Daubert v. Merrell Dow Pharm., Inc., 509 U.S. 579 (1993).

[89] *Cf.* Dempsey v. Shell Oil Co., 589 So.2d 373, 380 (Fla. Dist. Ct. App. 1991) (noting that, in the converse, expert testimony is inadmissible if based upon insufficient data).

V. METHODOLOGICAL APPENDIX

Table 3. Demographics, split by disclosure type and level of risk. The sample was less racially diverse, more often male, and younger than the U.S. population, but differences were successfully randomized across the five experimental conditions, and regression analyses further controlled for demographic covariates. Note: Due to rounding, listed percentages might not add to exactly 100%.

	None (*n*=116)		**Partial** (*n*=217)		**Full** (*n*=237)		**Subject Totals** (*N*=691)	**U.S. Census**
Education	**Low** (*n*=116)	**High** (*n*=121)	**Low** (*n*=108)	**High** (*n*=109)	**Low** (*n*=117)	**High** (*n*=120)		
< HS Diploma/GED	1 (1%)	1 (1%)	0 (0%)	2 (2%)	0 (0%)	1 (1%)	5 (1%)	18%
HS Diploma/GED	10 (9%)	13 (11%)	13 (12%)	13 (12%)	13 (11%)	10 (8%)	72 (10%)	30%
Some College/Assoc.	46 (40%)	49 (40%)	52 (48%)	41 (38%)	57 (49%)	58 (48%)	304 (44%)	27%
College Grad.	45 (39%)	51 (42%)	30 (28%)	42 (39%)	39 (33%)	39 (32%)	246 (36%)	17%
Grad. Degree	13 (11%)	7 (6%)	13 (12%)	11 (10%)	8 (7%)	12 (10%)	64 (9%)	10%
Gender								
Male	72 (62%)	72 (60%)	62 (57%)	72 (66%)	75 (65%)	84 (70%)	435 (63%)	49%
Female	44 (38%)	49 (40%)	46 (43%)	39 (36%)	42 (36%)	36 (30%)	256 (37%)	51%
Age Groups								
18-24	50 (43%)	47 (39%)	44 (41%)	41 (38%)	49 (42%)	53 (44%)	284 (41%)	13%
25-34	40 (34%)	38 (31%)	37 (34%)	35 (32%)	40 (34%)	38 (32%)	228 (33%)	18%
35-44	16 (14%)	21 (17%)	12 (11%)	23 (21%)	16 (14%)	17 (14%)	105 (16%)	19%
45-59	8 (7%)	14 (12%)	11 (10%)	8 (7%)	8 (7%)	11 (9%)	60 (9%)	27%
60+	2 (2%)	1 (1%)	4 (4%)	2 (2%)	4 (3%)	1 (1%)	14 (2%)	23%
Race								
White	94 (81%)	89 (74%)	89 (82%)	81 (74%)	97 (83%)	103 (86%)	553 (80%)	74%
Non-White	22 (19%)	29 (24%)	19 (18%)	26 (24%)	20 (17%)	17 (14%)	133 (19%)	26%